

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL

MINUTES OF MEETING

Immunization Practices Advisory Committee
June 23-24, 1987
Atlanta, Georgia

The Immunization Practices Advisory Committee (ACIP) met in Conference Room 207 at the Centers for Disease Control, Atlanta, Georgia, on June 23-24, 1987. Those in attendance are listed below:

COMMITTEE MEMBERS PRESENT

Dr. Samuel L. Katz, Chairman
Dr. Ellen S. Alkon
Dr. Jeffrey P. Davis
Dr. David S. Fedson
Dr. Anne A. Gershon
Dr. W. Paul Glezen
Dr. F. Marc LaForce
Dr. Edward A. Mortimer, Jr.
Dr. H. Denman Scott

Ex Officio Members

Dr. William S. Jordan, Jr. (NIH)
Dr. Elaine C. Esber (FDA)

Liaison Representatives

Dr. J. Michael Dixon (NACI)
Dr. William Schaffner II (ACP)
Dr. John M. Tudor, Jr. (AAFP)

Executive Secretary

Dr. Jeffrey P. Koplan

COMMITTEE MEMBERS ABSENT

Mrs. Betty F. Bumpers

Liaison Members

Dr. Albert W. Pruitt (AMA)
Dr. Stanley A. Plotkin (AAP)
Dr. Jarrett Clinton (DoD)

HHS STAFF PRESENT

FOOD AND DRUG ADMINISTRATION

Office of Biologics Research and Review
Dr. Carolyn Hardegree

CENTERS FOR DISEASE CONTROL

Office of the Director
Dr. James O. Mason

HHS STAFF PRESENT (continued)

CENTERS FOR DISEASE CONTROL

Center for Infectious Diseases

Ms. Nancy Arden
Dr. John Bennett
Dr. Claire Broome
Dr. Mitchell Cohen
Dr. John Feeley
Dr. Maurice Harnon
Dr. Alan Kendal
Dr. Olen Kew
Dr. Andrew Pavia
Dr. Nathan Shaffer
Dr. John Spika
Dr. Robert Tauxe

Center for Prevention Services

Dr. Roger Bernier
Dr. Robin Biellik
Dr. Edward Brink
Dr. Steven Cochil
Ms. Debra Combs
Ms. Jessica Gardom
Dr. Alan Hinman
Dr. Sonja Hutchins
Dr. J. Michael Lane
Dr. John Livengood
Mr. John Mullen
Dr. Walter Orenstein
Dr. Peter Patriarca
Dr. Stephen Preblud
Dr. Myron G. Schultz
Dr. Dixie Snider
Mr. Don Stenhouse
Dr. Walter Williams

Epidemiology Program Office

Dr. Robert Gunn

International Health Program Office

Dr. Ronald Waldman
Mr. Robert Baldwin
Dr. Kenneth Bernard

OTHERS PRESENT

Dr. Vincent Ahonkhai
 Dr. Joseph Bawduniak
 LT Christine Beadle, MC, USNR
 Mr. Gary Bridi
 Ms. Leslie Chapman
 Dr. Connie Cheng
 Dr. Pinya Cohen
 Dr. Corry Dekker
 CDR Mark Dembert, MC, USN
 Dr. H. Bruce Dull
 Dr. Marie R. Griffin

Dr. Jill Hackell
 Dr. Victor Jegede
 Dr. Andre LaMotte
 Dr. Ellen McGuire
 Dr. J. A. Morris
 Dr. Trudy Murphy
 Dr. Michael T. Osterholm
 Mr. Ronald Scroggins
 Dr. David Smith
 Dr. Paul Steele
 Dr. Roberto Suarez, Jr.

The meeting was opened at 8:30 a.m. on June 23 by Dr. Samuel L. Katz, Chairperson. Dr. Katz introduced a new member, Dr. F. Marc LaForce, Veterans Administration Medical Center, Denver, Colorado. Dr. Elaine Esber represented Dr. Paul Parkman, FDA.

Haemophilus influenzae Type b (Hib) Disease

Dr. Edward Mortimer reviewed a Haemophilus b Polysaccharide Vaccine Workshop held in Bethesda, Maryland, on April 20, 1987. The purpose of the workshop was to discuss available data on efficacy of the Haemophilus polysaccharide vaccine in the United States and the evidence for a possible association between vaccination and early onset disease. After a lengthy discussion on the preliminary post-marketing surveillance data on Hib capsular polysaccharide vaccines, Dr. Katz asked the committee whether the data presented warranted a change in the current recommendations. The consensus was that no change was warranted and that an ACIP update should be printed in the MMWR to this effect. Also, the update should emphasize that Hib vaccine should not be used as a substitute for prophylaxis with rifampin, when circumstances warrant such prophylaxis.

Sudden Infant Death Syndrome (SIDS)

Dr. John Livengood, Division of Immunization (IM), Center for Prevention Services (CPS), CDC, opened the discussion on the relationship of DTP immunization and SIDS.

Dr. Mortimer presented data from a study on SIDS after DTP immunization among a cohort of HMO members, by number of days after immunization (0-3, 4-7, 8-29, 30+). The observed number was compared to the expected derived from a group of controls in the HMO (Walker *et al.*, AJPH, in press). Overall, the risk of SIDS in the unvaccinated was greater than the risk in the vaccinated. Among the vaccinated, there was a small but statistically significant excess number of deaths within 3 days of vaccination compared to expected.

Dr. Marie R. Griffin, Vanderbilt University School of Medicine, Nashville, Tennessee, gave an overview of a large retrospective cohort study of Medicaid patients in Tennessee to ascertain whether rates of SIDS are higher immediately following DTP. Her data revealed that there was no increased risk for SIDS following DTP/OPV immunization in Tennessee children immunized in the public sector.

Dr. Livengood briefly reviewed several publications relating to DTP immunization and SIDS. In particular, he discussed data from the National Institute of Child Health and Human Development (NICHD) SIDS Cooperative Epidemiological Study, a large multicenter, population-based, case-control study. The results of the NICHD study suggest that DTP immunization is not a significant factor in the occurrence of SIDS. He also presented data on age distribution and observed versus expected distribution of SIDS cases after DTP vaccination in a Norwegian SIDS study (Report to the Oslo Health Council, 1985); unexpected infant deaths in Sheffield, England, 1979-1982; and comparison of SIDS rate and infant mortality rate in the Swedish SIDS study, 1973-1984. All of these later studies do not suggest a relationship with DTP and SIDS.

The committee concluded that the bulk of the available information does not implicate DTP as a cause of SIDS.

Poliomyelitis

Dr. Alan Hinman, IM, CPS, stated that plans are progressing for a symposium/workshop to clarify specific questions regarding policy for use of an improved poliomyelitis vaccine in the United States. This will be under the auspices of the Institute of Medicine, National Academy of Sciences, as previously discussed during the February 1987 ACIP meeting. Efforts to eradicate polio in the Americas by 1990 are proceeding. Recent polio outbreaks have occurred in Africa, Senegal, and The Gambia.

Dr. Peter Patriarca, IM, CPS, reviewed the status of an outbreak of type III polio in 1986 in Brazil, where OPV was used exclusively and where the efficacy rate appeared to be low, and discussed recommended measures for controlling the outbreak.

Dr. Olen Kew, Division of Viral Diseases (DVD), Center for Infectious Diseases (CID), discussed laboratory support efforts in eradicating Polio.

Bacillus Calmette and Guérin (BCG)

Dr. Dixie Snider, Jr., Division of Tuberculosis Control (DTBC), CPS, reviewed the Division's presentation on surveillance of tuberculosis and new data on BCG efficacy at the February 1987 ACIP meeting. Ms. Debra Combs, DTBC, gave data on risk of infection and disease among health-care workers in two teaching hospitals, and asked for comments on an updated draft which had been mailed to the committee for review before the meeting. Dr. Katz asked that any additional comments on the draft be sent to Dr. Koplan within 2 weeks.

Measles

Dr. Hinman stated that the revised recommendation on Measles Prevention will be published in July. The increase in the number of measles cases in 1986 is of concern. Unvaccinated preschool-aged children and vaccine failures in school-aged children are the major reasons for the increase. The highest incidence rate was reported among children less than 5 years of age, a result of several outbreaks involving a substantial proportion of preschool-age children in socioeconomically depressed urban areas. Preventable cases are the result of a failure to fully implement the current measles elimination strategy. A smaller proportion of reported cases occurred on college campuses

than in previous years. Increases in the number of reported cases have occurred annually since the record low (1,497 cases) in 1983.

Dr. Stephen Preblud, IM, presented data on the number of measles cases each year in the United States from 1950-1986, reported cases in the United States for 1985 (2,822) and 1986 (6,273), age distribution and preventability of cases in the United States in 1985-1986, and effects of age when receiving measles immunization. For the 6,273 cases in 1986, 36% were preventable.

Dr. Sonja Hutchins, IM, discussed vaccine efficacy and a revaccination program in an outbreak of 213 confirmed measles cases in New Mexico between January 15 and April 4, 1987. The data included the number of cases reported in New Mexico, by city, age distribution, and preventability; status of school-aged cases in Albuquerque; attack rates at the index high school by vaccination status; cases by school, and date of rash onset in relation to school-based revaccination clinics in Albuquerque; attack rates before and after vaccination clinics, by age; distribution and attack rates by school/university; and estimated cost of vaccines administered during revaccination clinics, March 3-April 14, 1987.

Rubella Update

Dr. Stephen Cochi, IM, stated that rubella rates in the United States were at an all-time low in 1986. He gave data on rubella incidence in 10 selected areas in the United States between 1928-1984. This included the average annual incidence rate, by age group, in the United States, 1966-1985; number of cases of congenital rubella syndrome (CRS), by year of birth, 1970-1986, and number of previous live births among mothers of CRS infants, by age, 1979-1985; and the risk of CRS following rubella vaccination, 1971-1986. The data on vaccination during pregnancy was reassuring. Dr. Katz suggested that the committee encourage more communication with the American College of Obstetrics and Gynecology.

Mumps Update

Dr. Cochi discussed the increase in mumps cases in 1987. From January-May of this year, 7,625 cases have been reported; for the corresponding period in 1986, 1,501 cases were reported. During 1986-1987, seven colleges and universities in three states reported 469 cases of mumps. He discussed the epidemiology of mumps in the United States from 1968-1986 and reviewed the current recommendations, issued November 28, 1982, on use of the mumps vaccine licensed in 1967. Published clinical studies of mumps vaccine efficacy (clinical trials and outbreak studies) reveal no waning vaccine immunity. Resurgence of mumps appears to be due to failure to vaccinate susceptible persons.

Human Immunodeficiency Virus (HIV)-Positive Children - Update

Dr. Alan Hinman, IM, discussed immunization of HIV-positive children. This included the number of pediatric AIDS cases reported to CDC as of February 2, 1987, adverse events in vaccinees, live virus vaccine received by HIV-infected children in New York City, live virus vaccine received after onset of symptoms of HIV infection, and total doses of OPV and MMR administered. During 1987, five cases of measles disease (2 fatal) have been reported in HIV-infected children in Miami and New York City.

The committee decided to change recommendations concerning measles vaccine and HIV-infected children for children with AIDS or other manifestations of HIV infection. The committee felt that measles vaccine should be administered as young as 6 months of age in settings of increased risk of measles exposure.

Cholera Vaccine Update

Dr. Nathan Shaffer, Division of Bacterial Diseases (DBD), CID, reviewed current recommendations, issued in 1978, and discussed field trials in Bangladesh and the Philippines. The vaccine is indicated only for travelers to countries requiring evidence of cholera vaccination for entry. Cholera is a health risk in Africa and Asia. Countries reporting cholera are listed in the publication Summary of Health Information for International Travel. After discussing administering yellow fever and cholera vaccines simultaneously, the committee agreed that these should be given at least 3 weeks apart, when possible. It was noted that this is addressed in the 1984 Adult Immunization recommendations. Dr. Katz asked Dr. Shaffer to prepare a new draft of the Cholera Vaccine statement which should include a paragraph on cholera and yellow fever for the committee to review.

Typhoid Vaccine Update

The epidemiology of typhoid in the United States was summarized by Dr. Andrew Pavia, DBD. In 1979, 62% of cases in the United States were acquired by travelers to other countries; this increased to 69% in 1984. The groups in the United States at greatest risk are travelers to other countries, microbiology workers, and those in close contact with carriers. He discussed vaccine composition and described field trials using heat-phenol and inactivated vaccine and live attenuated oral vaccine, which has not yet been licensed. The committee agreed that an updated recommendation should be drafted for use as soon as the oral vaccine is approved.

Progress in Acellular Pertussis Vaccine

Dr. Roger Bernier, IM, presented preliminary safety data from the Swedish acellular pertussis vaccine study. Safety and efficacy data are expected to be available by January 1988. Ms. Jessica Gardom, IM, presented updated information on ongoing or proposed studies on immunogenicity and safety of pertussis acellular vaccines.

Influenza

Ms. Nancy Arden, DVD, CID, stated that the new recommendation, "Prevention and Control of Influenza" for the 1987-1988 influenza season will be published in the MMWR on June 26, 1987.

Dr. Katz reviewed an action at the previous meeting in February when he asked Drs. Davis, Fedson, and Glezen to work with Dr. Alan Kendal's staff on development of provisional recommendations for use of rimantadine prophylaxis so these would be available when and if the FDA approval of the NDA (new drug application) is received. The group met on May 12, 1987, to draft specific recommendations for the use of this antiviral drug, and should this be approved for marketing in the United States, additional recommendations will be published.

Dr. Maurice Harmon, DVD, presented surveillance data of influenza activity in the Southern Hemisphere, from the WHO Collaborating Center for Influenza, CDC. This included hemagglutination-inhibition and neutralization reaction patterns of influenza B viruses, with Ferret antisera; summary of influenza B isolates received from foreign laboratories for March-June, 1987; and neutralization titers of pooled serum from young adults who responded to the B/Ann Arbor/1/86 component of inactivated vaccine. Influenza A(H1N1) viruses predominated, with outbreaks occurring mainly among children and young adults.

Vaccine Law - Update

Dr. Hinman reviewed the National Childhood Vaccine Injury Act of 1986, Title III, of PL 99-660, signed November 14, 1986, and gave the present status of legislation.

National Vaccine Program: The purpose of the Program is to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. As Director of the Program, Dr. Robert E. Windom is responsible for coordinating and providing direction for research carried out in or through NIH, CDC, FDA, DoD, and AID on means to induce human immunity against naturally occurring infectious diseases and to prevent adverse reactions to vaccines. The legislation calls for a National Vaccine Advisory Committee, with members appointed by the Director of the Program, to make recommendations to the Director. The Bill authorizes funding of the Program for 5 years: FY-1987, \$2M for general fund activities, \$20M additional for research; FY-1988-1991, increased by \$0.5M each year for general activities, \$2.5M for research. Appropriations have not been made to date.

National Vaccine Injury Compensation Program: Compensation may be paid for a vaccine-related injury or death for these vaccines: DTP, polio, measles, mumps, and rubella. There are general rules relating to compensation awards (limits, amount, death awards, attorney fees, punitive damage), and there are additional requirements.

Other ACIP Business

Dr. Katz introduced Mrs. Leslie Chapman, representing Dissatisfied Parents Together, who read a 3-page statement criticizing a supplementary recommendation, "Pertussis Immunization: Family History of Convulsions and Use of Antipyretics," dated May 15, 1987. This is a supplement to the current recommendation, "Diphtheria, Tetanus, and Pertussis: Guidelines for Vaccine Prophylaxis and Other Preventive Measures," dated July 12, 1985.

Dr. James O. Mason, Director of the Centers for Disease Control, presented certificates and letters of appreciation to Drs. Alkon, Gershon, and Mortimer whose committee appointments expired June 30.

Dr. William S. Jordan, Jr., NIH/NIAID ex officio member since 1976, will retire in October. He has made regular and significant contributions to the proceedings and products of the ACIP and, through these and his wide variety of other NIAID responsibilities, to the health of the people of the United States.

Dr. Katz announced that since the February meeting two new recommendations were published: Update on Hepatitis B Prevention, June 19, 1987, and Pertussis Immunization: Family History of Convulsions and Use of Antipyretics, May 15, 1987.

The fall committee meeting was scheduled for Wednesday and Thursday, October 28-29, 1987.

With the thanks of the Chairman, the meeting was adjourned at 12:15 p.m.

I certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.


Samuel L. Katz, M.D., Chairman 10-12-87
Date